

**REMARKS**

Reconsideration is requested.

Claims 1-10, 12 and 17-22 have been canceled, without prejudice. Claim 11 has been amended to provide a method of therapy, based on the disclosure, for example, of page 6 of the specification, and partially in response to the Examiner's comments in the first paragraph of page 11 of the Office Action dated January 14, 2004 (Paper No. 011004). No new matter has been added.

The Section 102 rejection of claims 11 and 13-22 over Lattanzi (May, 1998) (Journal Clinical Investigation, Volume 101 (10), 2119-2128), should be withdrawn as the identified document of Lattanzi was published after the filing of the presently claimed priority document. Attached is a copy of the International Search Report received in relation to PCT/EP99/03075, which indicates that Lattanzi was published May 15, 1998. As indicated in the Filing Receipt mailed January 10, 2001, the Italian priority document MI 98A001004 was filed May 8, 1998. Accordingly, Lattanzi is not submitted to be citable against the present application.

Withdrawal of the Section 102 rejection of claims 11 and 13-22 over Lattanzi is requested. The Examiner is requested to contact the undersigned if anything further is required in this regard.

The Section 103 rejection of claims 17-22 over Watt (WO 96/09373), Choi (PNAS (1990), Volume 87, 7988-7992) and Murry (Journal Clinical Investigation (1996), Volume 98 (10), 2209-2217), is obviated by the above amendments. As noted above, claims 17-22 have been canceled, without prejudice, to advance prosecution. Entry of the above amendments will, at a minimum, reduce the issues for any potential appeal

by obviating this Section 103 rejection of claims 17-22. Entry of the above amendments and withdrawal of the Section 103 rejection of claims 17-22 are requested.

The Section 103 rejection of claims 11 and 13-16 over Watt, Choi, Murry and Salvatori (Journal Cell Science (1995), Volume 108, 2733-2739), is believed to be obviated by the above amendments which provide a method of therapy, which is not believed to be taught or suggested by the cited art individually or in combination.

As noted, for example, in the applicant's remarks of October 17, 2003, the presently claimed invention provides therapeutically useful cells which can be used immediately after exposure to the transiently infecting vector, without any further culture step such as those described in the cited prior art, such as Choi. Such further culture steps invariably result in reduction of cell viability and increase cell aging. The Examiner has previously considered these arguments and has, in the applicant's view, suggested that the same may be given greater weight if the claims are cited of method of therapy, as the claims have been amended above. The applicant believes therefore that the above amendments do not raise new issues which would require further consideration and/or search. Entry of the above amendments and allowance of the amended claims are requested.

The Examiner is further requested to consider in this regard that in contrast to any item of the cited prior art, the method of myogenic conversion utilizes transient infection with non-integrating vectors, which allow substantially high conversion of fibroblasts ex vivo. In addition, the use of non-integrating viral vectors is safer for therapeutic applications. A further advantage, as described on page 5, last paragraph of the present application, is that no cell-mediated immune response has been

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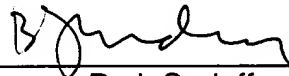
observed at the site of an infection of the modified fibroblasts, which the Examiner will appreciate is very advantageous.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned if anything further is required in this regard.

Respectfully submitted,

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## INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 99/03075

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
| A          | US 5 219 740 A (MILLER A DUSTY ET AL)<br>15 June 1993 (1993-06-15)<br>the whole document<br>---   |                       |
| A          | WEINTRAUB H ET AL: "ACTIVATION OF<br>MUSCLE-SPECIFIC GENES IN PIGMENT, NERVE,<br>FAT, LIVER, AND FIBROBLAST CELL LINES BY<br>FORCED EXPRESSION OF MYOD"<br>PROCEEDINGS OF THE NATIONAL ACADEMY OF<br>SCIENCES OF USA,<br>vol. 86, 1 July 1989 (1989-07-01), pages<br>5434-5438, XP000672860<br>ISSN: 0027-8424<br>the whole document<br>--- |                       |
| P,X        | LATTANZI L, ET AL.: "High Efficiency<br>Myogenic Conversion of Human Fibroblasts<br>by Adenoviral Vector-Mediated MyoD gene<br>transfer"<br>JOURNAL OF CLINICAL INVESTIGATION,<br>vol. 101, no. 10,<br>15 May 1998 (1998-05-15), pages 2119-2128,<br>XP002112711<br>page 2124 - page 2125<br>page 2127, column 2, paragraph 1<br>---        | 1-10                  |
| P,X        | HUARD C, ET AL.: "Transplantation of<br>Dermal Fibroblasts Expressing MyoD1 in<br>Mouse Muscles "<br>BIOCHEMICAL AND BIOPHYSICAL RESEARCH<br>COMMUNICATIONS,<br>vol. 248, no. 3,<br>30 July 1998 (1998-07-30), pages 648-654,<br>XP002112712<br>page 651, column 2, paragraph 1<br>-----  | 1-10                  |